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EXAMINER

FOX, DAVID T

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,966

Applicant(s)

ROITSCH, THOMAS G.

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-88 is/are pending in the application.
- 4a) Of the above claim(s) 50,55-59,62,70-72,74-85,87 and 88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-49,51-54,60,61,63-69,73 and 86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Applicant's election with traverse of Group I in the reply filed on 18 October 2004 is acknowledged. The traversal is on the ground(s) that different groups were presented during the examination of the parent PCT application. This is not found persuasive because the Lack of Unity set forth by the instant Examiner is in compliance with the rules, the Examiner is not bound by the prosecution of another Examiner, and different claim sets were presented in the PCT and the National Phase applications.

The requirement is still deemed proper and is therefore made FINAL.

Claims 45-49, 51-54, 60-61, 63-69, 73 and 86 are examined in the Office action that follows. Upon further consideration, claim 49 has been examined with Group I, since SEQ ID NO:2 encompasses SEQ ID NO:1. Claims 50, 55-59, 62, 70-72, 74-85 and 87-88 are withdrawn as being drawn to a non-elected invention.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 45-49, 51-52, 61, 63-69 and 86 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The DNA molecule, as claimed, has the same characteristics and utility as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

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Furthermore, the seeds of claims 68-69 need not contain any foreign gene, due to Mendelian segregation of single genes during outcrossing, and would thus be indistinguishable from naturally occurring seeds.

The following amendments would obviate the rejection above:

In claims 45-49, line 1, replace "Nucleic" with ---An isolated nucleic---

In claim 51, line 2, insert ---isolated--- before "nucleic".

In claim 61, line 2, replace "a nucleic" with ---an isolated nucleic---

In claims 68-69, insert before the period: ---, wherein said seed comprises said isolated nucleic acid sequence---

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45-49, 51-54, 60-61, 63-69, 73 and 86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

Claims 45, 49, 51, 60-61 and 73 are indefinite in their recitation of "coding for a...promoter" which is contrary to art-recognized definitions, as nucleic acid sequences code for proteins, while a promoter is another DNA sequence. Replacement of "coding for" with ---comprising--- would obviate this rejection.

Claims 45-47, 51, 60-61 and 73 are indefinite in their recitation of "range of at least X nucleotides" as it is unclear whether the nucleotides are contiguous or

dispersed. If intended, amendment of the claims to insert ---contiguous--- before “nucleotides” would obviate this rejection.

Claims 45-47, 49, 51, 60-61 and 73 are indefinite in their recitation of “the sequence represented in SEQ ID NO:X” as it is unclear whether the intended sequence comprises that found in the Sequence Listing, or whether the Sequence Listing is only a representative example of the genus of sequences intended by Applicant. If intended, deletion of “sequence represented in” would obviate this rejection.

Claims 53, 60-61, 63 and 66 are indefinite in their recitation of “selected from the group comprising” which employs improper Markush terminology. Replacement of “comprising” after “group” with ---consisting of--- would obviate this rejection. See MPEP 2173.05(h).

Claims 53 and 60-61 are indefinite in their recitation of “expressible nucleic acid...direct or indirect action and functional nucleic acids” which is unduly narrative and confusing. The actual Markush group being claimed is unclear, as the individual species present are unclear. Furthermore, it is unclear what constitutes “direct” or “indirect action”. Moreover, it appears that all nucleic acid molecules are “functional” in some manner, so that the adjective fails to further describe the noun it modifies. If Applicant intends another definition of these terms, it would appear to be contrary to art-recognized usage. See MPEP 2173.03 and 2173.05(a).

Claim 64 is indefinite in its recitation of “arrested pollen cell” as it is unclear what is intended, and it is unclear whether whatever is intended is an art-recognized usage of the term. See MPEP 2173.03 and 2173.05(a).

Claim 66 is indefinite in its recitation of "preferably" which fails to positively recite required claim elements. It is unclear whether the subject matter recited after "preferably" is required or merely exemplary. The claim is also indefinite for reciting a range within a range.

Claims 67 and 86 are indefinite in their recitation of "particularly" which fails to positively recite a required claim element. It is unclear whether the subject matter recited after "particularly" is required or merely exemplary.

Claims 67 and 69 are indefinite in their recitation of "male, sterile" and "male, fertile". "Male, sterile" could be interpreted as a plant which produces functional male organs, but is otherwise sterile (i.e. female sterile). If Applicant intended to recite a plant which fails to produce functional male organs or male reproductive structures, the comma between "male" and "sterile" should be removed. Similarly, "male, fertile" could also imply a female sterile flower which is male fertile. If Applicant intended to recite a flower which produces functional male organs, but did not intend to limit the functionality of the female organs, then the comma between "male" and "fertile" should be removed.

Claim 69 is further indefinite in its recitation of "hybridized with" which is employed contrary to its art-recognized usage. "Hybridized with" is generally used to refer to DNA/DNA binding assays, rather than outcrossing to a different plant genotype, as apparently intended by Applicant. See MPEP 2173.03 and 2173.05(a).

Claim 69 is also indefinite in its recitation of "obtainable in that" which is unduly narrative, and which fails to positively recite a required claim element. Does Applicant intend that the seed be made in a way different from the claimed process?

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Claim 73 is indefinite in its mere recitation of "involving", which fails to positively recite any method steps to be used in carrying out the claimed process.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 45-49, 51-52, 61, 63-69 and 86 are rejected under 35 U.S.C. 102(b) as being anticipated by Greiner et al (1996, Applicant submitted).

The claims are broadly drawn to tobacco plants comprising a genome comprising a tapetum- and pollen- specific invertase gene which comprises its promoter operably linked to its native coding sequence, and parts thereof including fruit and seeds. Claims 68-69 also read on seeds produced by crossing a transformed plant with an untransformed plant, wherein half of the seeds would not contain the transgene, due to Mendelian segregation, and so would be indistinguishable from an untransformed tobacco plant.

Greiner et al teach tobacco plants, including transformed tobacco plants (see, e.g., page 734, column 1, penultimate paragraph).

Regarding claims 68-69, see *In re Best*, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Amending the claims to overcome the rejections under 35 USC 101 and 112 would obviate this rejection.

Claims 53-54, 60 and 73 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated promoter comprising at least 900 contiguous base pairs upstream of the TATA box of SEQ ID NO:1 or 2, nucleic acid constructs or vectors containing the promoter, and methods of its use.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy J. Nelson, Ph.D., can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 26, 2004

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

